Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
Case No.: 1:19-cv-272-LCB-LPA

MAXWELL KADEL, et al.,	)
	)
Plaintiffs;	)
v.	)
	)
DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, et al,	)
	)
Defendants.	)

Declaration of
STEPHEN B. LEVINE, M.D.
Version of APRIL 28, 2021

SECTION I. CREDENTIALS - KNOWLEDGE, TRAINING, and EXPERIENCE:

1. Education - Academic Appointments - Research Grants: I am a Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine, and also maintain an active private clinical practice. I received my MD from Case Western Reserve University in 1967, and completed a psychiatric residency at the University Hospitals of Cleveland in 1973. I became an Assistant Professor of Psychiatry at Case Western in 1973, and became a Full Professor in 1985. I have been the recipient of the following grants for scientific research and/or program development:

a. 23 separate pharmaceutical company grants to study various prosexual medications

b. U.S. National Institute of Health grant for the study of sexual consequences of Systemic Lupus Erythematosis. Co-principal investigator

3. Founder of the Case Western Gender Identity Clinic - former WPATH Chairman of the Standards of Care Committee: I first encountered a patient suffering what we would now call gender dysphoria in July 1973. In 1974, I founded the Case Western Reserve University Gender Identity Clinic, and have served as Co-Director of that clinic since that time. Across the years, our Clinic evaluated and treated hundreds of patients who were experiencing a transgender identity. An occasional child was seen during this era. I was the primary psychiatric caregiver for several dozen of our patients and supervisor of the work of other therapists. I was an early member of the Harry Benjamin International Gender Dysphoria Association (later known as WPATH) and served as the *Chairman of the WPATH Standards of Care Committee* that developed the 5th version of its Standards of Care. In 1993 the Case Western Reserve University Gender Identity Clinic was renamed, moved to a new location, and became independent of Case Western Reserve University. I continue to serve as Co-Director. In 2020, the clinic was renamed the Gender Diversity Clinic.

4. Court Appointed Expert: In 2006, Judge Mark Wolf of the Eastern District of Massachusetts asked me to serve as an independent, court-appointed expert in a litigation involving the treatment of a transgender inmate within the Massachusetts prison system. After providing a six-hour workshop to the mental health professionals in the system, I was retained by the Massachusetts Department of Corrections in 2007 as a consultant on the treatment of transgender inmates. I have been in that role continuously since.

5. Experience as an Expert Witness: I was qualified as an expert and testified concerning the diagnosis, understanding, developmental paths and outcomes, and therapeutic treatment, of transgenderism and gender dysphoria, particularly as it relates to children, in 2019 in the matter of *In the Interest of J.A.D.Y. and J.U.D.Y.*, Case No. DF-15-09887-S, 255th Judicial District,

youth and that for any 16 or 17 year old to obtain hormonal therapy for gender dysphoria they must have court approval for its administration.

k. London 2 : In the High Court of Justice Queen's Bench Division administrative court. The Queen (on the application of) L. and Hampshire County Council. (A matter of education about transgender identities in schools; not yet decided.)

l. Expert in this case Kadal v. Folwell: I have been retained by the defense in this case to serve as an expert witness. My compensation is $400 per hour and such payments are in advance of any written opinions to avoid conflicts of interest and independent judgment.

7. A more complete review of my professional experience, publications, and awards is provided in my curriculum vitae, a copy of which is attached hereto as Exhibit A.

8. Summary of Issues: In this declaration, I offer information and my expert opinions concerning a number of aspects of the phenomenon of Gender Dysphoria and transgender identity (i.e., Gender Discordance, Gender Incongruity), as well as a discussion of competing views among mental health and other professionals as to the appropriate assessment and therapeutic methods-practices for patients who experience gender dysphoria. At many points in this statement, I provide citations to published, peer-reviewed articles that provide foundational or additional supporting or relevant information. A summary of the key points I discuss in this statement includes:

a. Sex as defined by biology and reproductive function cannot be changed. While hormonal and surgical procedures may enable some individuals to "pass" as the opposite gender during some or all of their lives, such procedures carry with them physical, psychological, and social risks, and no procedures can enable an individual to perform the reproductive role of the opposite sex. (Section II.A.)

b. The diagnosis of "gender dysphoria" encompasses a diverse array of conditions, with widely differing pathways and characteristics depending on age of onset among other things. Data from one population (e.g. adults) cannot be assumed to be applicable to others (e.g. children). (Section II.B.)

c. Among psychiatrists and psychotherapists who practice in the area, there are currently widely varying views concerning both the causes of and appropriate therapeutic response to gender dysphoria. Existing studies do not provide a basis for a reliable scientific conclusion as to which therapeutic responses result in the best long-term outcomes for affected individuals — thus the field remains in an experimental stage. (Sections II.E, II.F.)

d. For example, a majority of children (in several studies, a large majority) who are diagnosed with gender dysphoria "desist"—that is, their gender dysphoria does not persist—by puberty or adulthood. It is not currently known how to distinguish children who will persist from those who will not — thus the majority of patients will do best with no "affirmation" treatments in childhood and we cannot reliably determine which patients would do better with "affirmation" treatments which can involve life-long damage to healthy organs and natural biological processes. (Section IV.) See consistent findings in detailed discussions of the new National Gender Dysphoria Review Guidelines from Sweden, Finland, England, the Cochrane Review, and sciencearticles below.

e. Some recent studies suggest that active affirmation of transgender identity in young children will substantially reduce the number of children naturally outgrowing or "desisting" from transgender identity. This raises ethical and public health concerns that "affirmation" treatments will increase the number of individuals who suffer the multiple long-term

physical, mental, and social limitations that are strongly associated with living life as a transgender person. (Section IV.)

f. Thus, social transition is itself an important intervention with profound implications for the long term mental and physical health of the child. When a mental health professional evaluates a child or adolescent and then recommends social transition, presumably that professional is available to help with interpersonal, familial, and psychological problems that may arise. However, many adolescents transition without mental health assessment and ongoing care, leaving themselves and their families on their own to deal with subsequent problems. (Section IV.)

g. In most cases, parental involvement is necessary for an accurate and thorough diagnosis of a child or adolescent presenting with gender dysphoria or a desire for a transgender identity, as well as for effective psychotherapeutic treatment and support of the young person. (Section V.)

h. The knowledge base concerning the cause and treatment of gender dysphoria available today has been repeatedly characterized in multiple reviews as of "low scientific quality". (Section VI.) (See detailed analysis below).

i. There are currently no studies that show that affirmation of transgender identity in young children reduces suicide, suicidal ideation, or improves long-term outcomes as compared to other therapeutic approaches. Meanwhile, multiple studies show that adult individuals living transgender lives suffer much *higher* rates of suicide and *negative* physical and mental health conditions than does the general population thus it remains unclear how much benefit, if any, is provided by the experimental treatments required for medical transitioning. (Section VI.)

j. In light of what is known and not known about the impact of affirmation on the incidence of suicide, suicidal ideation, and other indicators of mental and physical health, it is *scientifically baseless and unethical* to assert that a child or adolescent who expresses an interest in a transgender identity will kill him or herself — or is more likely to do so — unless adults and peers affirm that child in a transgender identity. (Section VI.)

k. Putting a child or adolescent on a pathway towards life as a transgender person puts that individual at risk of a wide range of long-term or even life-long harms, including: sterilization (whether chemical or surgical) and associated regret and sense of loss; inability to experience orgasm (for trans women); physical health risks associated with exposure to elevated levels of cross-sex hormones; surgical complications and life-long after-care; alienation of family relationships; inability to form healthy romantic relationships and attract a desirable mate; elevated mental health risks. (Section VII.) In my opinion, putting children through such risks who are very likely to naturally grow out of gender dysphoria into acceptance of their biological sex and gender is an experimental and unethical practice. This is especially true given the affirmation treatments have untested and unproven long-term outcomes.

l. Informed consent is ethically required for potentially life-altering psychological or medical procedures. However, the informed consent process in such complex cases is also complex. In some cases, it may not be possible to obtain meaningful informed consent to place a child on a psychological pathway that carries with it lifetime risks of the serious injuries, harms, and damages (including sterilization, limited sexual response, and social marginalization) that I detail in this report. A child is not competent, of course, to weigh how these potentially devastating life-long risks and issues will impact his or her lifetime happiness. At a minimum, informed consent of parents is essential, although it may not be sufficient. Withholding accurate information

— from patients or parents — on risks and benefits or misrepresenting the current state of research in this controversial field should be viewed as a serious ethics violation and reported to the proper licensing authorities. There is substantial evidence from science publications and also from journalist research that the "affirmation" treatment industry (i.e., often referred to as the Transgender Treatment Industry) is providing misleading information to the public and the legal system. For example, it is not the case that puberty halting hormone treatments are "easily reversed". (Section VIII.)

m. Research reviews support my opinion that gender affirmation treatments remain experimental and have never been accepted by the relevant scientific community and have no known nor published error rate — meaning the rates of clinical errors as manifested by desistance, increased mental suffering, educational failure, vocational inconstancy, or social isolation have not been established. See, e.g., Haupt, C., Henke, M. et. al., Cochrane Database of Systematic Reviews Review Intervention, Antiandrogen or estradiol treatment or both during hormone therapy in transitioning transgender women, 28 November 2020 ; See, e. g., Swedish Agency for Health Technology Assessment and Assessment of Social Services, SBU Policy Support no 307, 2019 www.sbu.se/en • registrator@sbu.se Contact SBU: Jan Adolfsson, Medical Advisor, Project Manager, jan.adolfsson@sbu.se, English Proofreading: Project group and Jan Adolfsson, SBU ["*No relevant randomized controlled (treatment outcome) trials in children and adolescents were found."]*

Within the last two years, detailed research reviews exposing multiple and serious methodological and ethical flaws in the research of Bränström, and Panchankis and Turban, and other "affirmation" supporters have pinpointed fundamental methodological errors in their papers which claim to support affirmation treatment. These reviews, also support my opinions that gender

affirmation treatments remain experimental and have never been accepted by the relevant scientific community and have no known nor published error rate. See, Kalin N. H. (2020). Reassessing Mental Health Treatment Utilization Reduction in Transgender Individuals After Gender-Affirming Surgeries: A Comment by the Editor on the Process. *The American journal of psychiatry*, *177*(8), 764. https://doi.org/10.1176/appi.ajp.2020.20060803; Biggs M. (2020). Puberty Blockers and Suicidality in Adolescents Suffering from Gender Dysphoria. *Archives of sexual behavior*, *49*(7), 2227–2229. https://doi.org/10.1007/s10508-020-01743-6; D'Angelo, R., Syrulnik, E., Ayad, S., Marchiano, L., Kenny, D. T., & Clarke, P. (2020). One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. *Archives of sexual behavior*, 10.1007/s10508-020-01844-2. Advance online publication. https://doi.org/10.1007/s10508-020-01844-2;

n. Bases for Expert Opinions and Review-Opinions regarding the Expert Declarations in this case by Drs. Schechter and Brown. I have reviewed dozens of scientific articles, national science reviews and guidelines (England (NICE), Sweden, Finland, Cochrane Review, association positions, the Complaint and Answer in this case, the plaintiff's medical records, and all expert declarations in this case. I have formulated opinions regarding the reports by Drs. Schechter and Brown. In my opinion, Drs Schechter and Brown failed to properly disclose and discuss the ongoing international debates and controversies as to whether Transgender Treatment Industry methods and procedures are unproven, experimental, and potentially more harmful than helpful to vulnerable patients. Similarly, Drs Schechter and Brown failed to properly disclose and discuss the recent and very public exposes documenting significant methodological failures and flaws in trans treatment science. Finally, Drs Schechter and Brown failed to report or discuss the recently published national reviews and research documenting the "weak" and methodologically defective

research foundations of the Transgender Treatment Industry including recent reviews from Great Britain (NICE), Sweden, Finland, the Cochrane Review, the 2020 Carmichael report, the Griffin study, the Zucker study and other important work published within the last 24 months.. [See, e.g. Carmichael P, Butler G, Masic U, et al. Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. medRxiv 2020.12.01.20241653; doi:https://doi.org/10.1101/2020.12.01.20241653 https://www.medrxiv.org/content/10.1101/2020.12.01.20241653v1

BBC summary: https://www.bbc.com/news/uk-55282113journal.pone.0243894. pmid:33529227], and Devita Singh, Susan J. Bradley and Kenneth J. Zucker, Frontiers in Psychiatry, March 2021 | Volume 12 | Article 632784, www.frontiersin.org] and related research discussed in detail below.

SECTION II. BACKGROUND IN THIS FIELD

A. The biological base line of sex

9. Sex is permanently "assigned" at conception by DNA: The sex of a human individual at its core structures the individual's biological reproductive capabilities—to produce ova and bear children as a mother, or to produce semen and beget children as a father. Sex determination occurs at the instant of conception, depending on whether a sperm's X or Y chromosome fertilizes the egg. Medical technology can be used to determine a fetus's sex before birth. It is thus not scientifically correct to talk of doctors "assigning" the sex of a child at birth; almost anyone can accurately and reliably identify the sex of an infant by genital inspection. What the general public may not understand, however, is that every nucleated cell of an individual's body is chromosomally identifiably male or female—XY or XX. Claims that patients can obtain a "sex change" or a "gender transition" process are misleading and scientifically impossible. In reality, the typical "transgender" Gender Discordant patient has normal healthy sex organs but struggles

with Gender Discordant feelings and perceived identity. Such patients can receive cosmetic surgeries and hormone treatment — but such methods never actually "transition" a patient to "another sex." In my opinion, these views are generally accepted by the relevant scientific community in the fields of biology, zoology, neonatology, genetics, pediatrics, and psychiatry.

10. The self-reported gender of a child, in contrast, arises in part from how others label the infant: "I love you, son (daughter)." This designation occurs thousands of times in the first two years of life when a child begins to show awareness of the two possibilities. As acceptance of the designated gender corresponding to the child's sex is the natural outcome in >99% of children everywhere, anomalous gender discordant identity formation begs for understanding. Is it biologically shaped or influenced? Is it biologically determined? Is it the product of how the child was privately regarded and treated? Does it stem from trauma-based rejection of maleness or femaleness, and if so flowing from what trauma? Is it a symptom of another, as of yet unrevealed emotional disturbance? Is it the result of a social contagion process — such as anorexia or bulimia may be, or from Internet involvement with trans websites? The ongoing scientific, clinical, and societal debate over such issues awaits reliable answers; while some offer authoritative opinions on these questions, they are not scientifically proven. In my opinion, these views are generally accepted by the relevant scientific community.

11. Under the influence of hormones secreted by the testes or ovaries, numerous additional sex-specific differences between male and female bodies continuously develop postnatally, culminating in the dramatic maturation of the primary and secondary sex characteristics with puberty. These include differences in hormone levels, height, weight, bone mass, shape and development, musculature, body fat levels and distribution, and hair patterns, as well as physiological differences such as menstruation. These are genetically programmed biological

consequences of sex which also serve to influence the consolidation of gender identity during and after puberty. In my opinion, these views are generally accepted by the relevant scientific community.

12. Despite the increasing ability of hormones and various surgical procedures to reconfigure some male bodies to visually pass as female, or vice versa, the biology of the person remains as defined by his (XY) or her (XX) chromosomes, including cellular, anatomic, and physiologic characteristics and the particular disease vulnerabilities associated with that chromosomally-defined sex. For instance, the XX (genetically female) individual who takes testosterone to stimulate certain male secondary sex characteristics will nevertheless remain unable to produce sperm and father children. Contrary to assertions and hopes that medicine and society can fulfill the aspiration of the trans individual to become "a complete man" or "a complete woman," this is not biologically attainable. It is possible for some adolescents and adults to pass unnoticed as the opposite gender that they aspire to be—but with limitations, costs, and risks, as I detail later. See, S. Levine (2018), Informed Consent for Transgendered Patients, J. of Sex and Marital Therapy, at 6, DOI: 10.1080/0092623X.2018.1518885 ("Informed Consent"); S. Levine (2016), Reflections on the Legal Battles Over Prisoners with Gender Dysphoria, J. American Academy of Psychiatry and Law 44, 236 at 238 ("Reflections"). In my opinion, these views are generally accepted by the relevant scientific community.

B. Definition and diagnosis of gender dysphoria

13. Specialists have used a variety of terms over time, with somewhat shifting definitions, to identify and speak about a distressing incongruence between an individual's sex as determined by their chromosomes and their thousands of genes, and the gender with which they eventually subjectively identify or to which they aspire. Today's American Psychiatric

Association's *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5) employs the term Gender Dysphoria and defines it with separate sets of criteria for adolescents and adults on the one hand, and children on the other. It is important to note that the DSM is not a reliable-valid scientific journal publication. The DSM began as an attempt to create a dictionary for psychiatry.The process by which DSM classifications are created involves voting by committee — this is nota reliable-valid scientific process. The committees' recommendations are approved or rejected by superordinate committees. DSM content is largely decided by consensus-seeking methodologies — such as "voting" by small committees of advocates and activist practitioners whose judgment may suffer from significant financial conflicts of interest — as appears to be the case with all three of the plaintiff's experts in this case. The limitations of the DSM methodology are well known in the relevant scientific community. See, e.g., Lee, C., *The NIMH Withdraws Support for DSM-5: The latest development is a humiliating blow to the APA*. Psychology Today News Blog at https://www.psychologytoday.com/us/blog/side-effects/201305/the-nimh-withdraws-support-dsm-5 ["Just two weeks before DSM-5 is due to appear, the National Institute of Mental Health, the world's largest funding agency for research into mental health, has indicated that it is withdrawing support for the APA's manual. In a humiliating blow to the American Psychiatric Association, Thomas R. Insel, M.D., Director of the NIMH, made clear the agency would no longer fund research projects that rely exclusively on DSM criteria. Henceforth, the NIMH, which had thrown its weight and funding behind earlier editions of the manual, would be "re-orienting its research away from DSM categories."] In my opinion, these views are generally accepted by the relevant scientific community.

14. There are at least five distinct pathways to gender dysphoria: early childhood onset; onset near or after puberty with no prior cross gender patterns; onset after homosexual lifestyle;

adult onset after years of heterosexual transvestism; and onset in later adulthood with few or no prior indications of cross-gender tendencies or identity. The early childhood onset pathway and the more recently observed onset around puberty pathway are relevant to this matter. Whereas, the onset of cross-gender identifications in the preschool years suggests temperamental and intrafamilial shaping forces, the post pubertal onset of what is now commonly referred to a rapid onset gender dysphoria seems to be heavily influenced by social forces. These derive primarily from the Internet and educational environments. The vulnerability to such social contagion may stem from conspicuous or subtle mental health problems or the child's misunderstanding of the normality of early pubertal discomfort with one's body, previous peer relationships, and despair about future gender-based social roles. The newly acquired trans identity is often passionately held as it explains away past and current unhappiness and emotional or behavioral problems.

Changing Complexities in Young Gender Dysphoric (GD) Patients

15. The Social Contagion Hypothesis. To avoid the methodological error of confirmation bias, clinicians and researchers generate and test alternative hypotheses. It is currently unclear how many new gender discordant patients have been influenced by social contagion processes. During the last 10-15 years, there have been multiple reports from multiple nations reporting a dramatic increase in the number of gender discordant patients as well as a dramatic change in the reported sex ratio of young patients presenting to clinics with trans gender identities. In the 20th century, the biologic male to biologic female ratio was consistently 3-4:1 in most North American and European clinics. Now some clinics are reporting a 7:1 ratio of girls to boys. Biological theories of gender dysphoria (e.g., "immutable", genetic, brain structures, etc.) appear unlikely to explain large, rapid demographic shifts in gender discordant patients. A social contagion - social influence theory has arisen in an attempt to help explain these dramatic demographic changes. In decades

past, gender discordant children and teens typically aspired to become a member of the opposite sex while more recently, patients are increasingly likely to define themselves as "non-binary persons" meaning that they have elements of both sex-genders within them or they have none of these elements. Such teens often report being influenced by trans websites and trans "influencers" on internet sources such as video blogs on YouTube. These onsite shows reportedly reach millions and teach adolescents to consider their problems, worries, discomforts, and anticipated social roles to be typical experiences of the unfolding of a biologically-determined trans self. In addition to YouTube and other internet sources, patients reportedly have been influenced by school trans awareness training programs teaching the normality of trans current and future lives — without an accurate discussion or depiction of the known risks and benefits.

A multi-disciplinary analysis that includes developmental psychology and the history of psychiatry provides additional support for the socialization hypothesis. Mental health professionals have long experience with adolescent females experiencing social worries that help to create anorexia nervosa, bulimia, and self-harm through cutting, burning, and piercings. Prof. Amanda Rose at the University of Missouri has conducted research to understand why adolescent girls demonstrate heightened susceptibility to a social contagion of psychiatric symptoms. She reports that" teenage girls share symptoms via social contagions because their friendship processes involve "co-rumination"— that is, taking on the emotional pain and concerns of their friends. This is a potential — and as yet uninvestigated hypothesis — as to the reports of" clusters" and "friend groups" of teen girls who are adopting trans identity and "transitioning" together (See, L. Littman (2018), *Parent Reports of Adolescents & Young Adults Perceived to Show Signs of a Rapid Onset of Gender Dysphoria*, PLoS ONE 13(8): e0202330 at 13). Prof. Rose's investigations note that adolescent girls seem more willing to adopt a friend's pain and even suspend reality to "get on the

symptom team" of their friends. (See, R. Schwatz-Mette and A. Rose, Co-Rumination Mediates Contagion of Internalizing Symptoms Within Youths' Friendships, Developmental Psychology 48(5):1355-65, February 2012, DOI: 10.1037/a0027484 Further, reliable-valid scientific research is needed to address these complex issues. See also, McCall, B. andNainggolan, L., Medscape *Transgender Teens: Is the Tide Starting to Turn?* https://www.medscape.com/viewarticle/949842#vp_1 ["The vast majority of youth now presenting with gender dysphoria are adolescents who suddenly express revulsion with their sex from birth, and 70% of them were born female. Many of them have comorbidities such as anxiety, attention deficit hyperactivity disorder, autism spectrum traits, and depression, Malone explains, which need to be considered. This newer presentation — which has been termed late-, adolescent-, or rapid-onset gender dysphoria — has now been seen in every gender clinic in the western world, and there has been a huge surge in the number of cases. One recent US survey found a 4000% increase (over 40-fold) since 2006, and there have been similar large increases reported in Finland, Norway, the Netherlands, Canada, and Australia. The London GIDS clinic reported a 30-fold increase in referrals over the past decade – and again they were primarily adolescent girls who said they now identify as boys.

It should be noted that rapid, unpredicted changes in the demographics of trans patients (i.e., from chronically discordant, early onset males to rapid onset adolescent females) calls into question the usefulness and accuracy of predictions emanating from research conducted on previous, demographically and clinically different patient groups. This again highlights the complex, little known, and experimental nature of trans phenomenon as well as the experimental treatment methods of the current Transgender Treatment Industry. See, rapid and unpredicted demographic changes: [A US survey found a 4000% increase (over 40-fold) since 2006]

"National College Health Assessment: ACHA-NCHA s://www.acha.org/NCHA/ACHA-NCHA_Data/Publications_and_Reports/NCHA/Data/Publications_and_Reports.aspx?hkey=d5fb767c-d15d-4efc-8c41-3546d92032c5 ; similar large increases have been reported in Finland: Kaltiala-Heino, Riittakerttu, Hannah Bergman, Marja Työläjärvi, and Louise Frisen. "Gender Dysphoria in Adolescence: Current Perspectives." *Adolescent Health, Medicine and Therapeutics* Volume 9 (March 2018): 31–41. https://doi.org/10.2147/AHMT.S135432 ; and in Norway ; and in the Netherlands: de Vries, Annelou L.C. de. "Challenges in Timing Puberty Suppression for Gender-Nonconforming Adolescents." *Pediatrics* 146, no. 4 (October 2020): e2020010611. https://doi.org/10.1542/peds.2020-010611. ; and in Canada: Zucker, Kenneth J. "Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues." *Archives of Sexual Behavior* 48, no. 7 (October 2019): 1983–92. https://doi.org/10.1007/s10508-019-01518-8, and others.

16. Gender dysphoria has very different characteristics depending on age and sex at onset. Young children who are living a transgender identity commonly suffer materially fewer symptoms of concurrent mental distress than do older patients. (See, K. Zucker (2018), The Myth of Persistence: Response to "A Critical Commentary on Follow-Up Studies & 'Desistance 'Theories about Transgender & Gender Non-Conforming Children" by Temple Newhook et al., Int'l J. of Transgenderism at 10, DOI: 10.1080/15532739.2018.1468293 ("Myth of Persistence"). The developmental and mental health patterns for each of these groups are sufficiently different that data developed in connection with one of these populations cannot be assumed to be applicable to another.

17. The criteria used in DSM-5 to identify Gender Dysphoria ("Gender Incongruence" is another term used) include a number of signs of discomfort with one's natal sex and vary

somewhat depending on the age of the patient, but in all cases require "clinically significant distress or impairment in important areas of functioning" such as social, school, or occupational settings. When these criteria in children, (or adolescents, or adults) are not met, two other diagnoses may be given. These are: Other Specified Gender Dysphoria and Unspecified Gender Dysphoria. Specialists sometimes refer to children who do not meet criteria as being "subthreshold."

18. In a complex, experimental, and little understood field such as transgender medicine, generating and exploring alternative hypotheses is essential to our efforts to help alleviate the tragic suffering of our patients. One such alternative is to teach coping and resilience skills to gender discordant children. Such training could include a realization that a wide range of behaviorsare available within their biologically concordant gender roles. Acquiring a broader perspective on the patient's natal sex roles might be a better solution for some than permanent damage to healthy sex organs via hormone and surgical "transitioning" procedures. Children who conclude that they are transgender are often unaware of a vast array of adaptive possibilities for how to livelife as a man or a woman—possibilities that become increasingly apparent over time to both malesand females. A boy or a girl who claims or expresses interest in pursuing a transgender identity often does so based on stereotypical notions of femaleness and maleness that are based on constrictive notions of what men and women can be. See, S. Levine (2017), Ethical Concerns About Emerging Treatment Paradigms for Gender Dysphoria, J. of Sex & Marital Therapy at 7, DOI: 10.1080/0092623X.2017.1309482 ("Ethical Concerns"). A young child's, even an adolescent's, understanding of this topic is quite limited. Nor do they have the perspective that discomfort with the body and perceived social role is not new to civilization; what is new is the option to become a trans person.

With most complex behavioral problems of child and adolescents, patients and families receive psychiatric attention that includes a thorough developmental history from parents, prolonged interviews with the patient, and a therapeutic approach which involves to some extent the parents, the patient, and the three together with or without medication assistance. Tragically, in too many gender clinics, young patients are not treated with the standard of care, complex, multi-disciplinary, evidence-based approach. Children are too often quickly referred to gender "specialists" — which generally means therapists who deeply believe (based on clinical-political ideology and not the relevant science) that every young person who is questioning his or her gender identity or declaring a trans identity should be quickly affirmed and supported in their atypical identity. Moreover, the ideological fashions of these therapists and the organizations that support them have effectively convinced many — contrary to the relevant science — that any other approach to these youth is dangerous, harmful, and might even lead to suicide. Other evidence-based, more methodologically sound approaches such as the generation and testing of alternative hypotheses as required by proper health care standards — are denigrated and ideologically labeled "conversion therapy."

The ideologically based indoctrination efforts to ban evidence based alternative treatments as "conversion therapy" can have harmful effects on our vulnerable patients. For example, many traditional therapists claim to not know how to take care of these gender discordant patients, as though they are not children who are suffering. This rationalization may only be a reflection of the fear of being attacked for performing dreaded, and now in some locations, illegal, "conversion therapy". In this way, qualified mental health professionals have failed to develop a robust experience with alternative ways of investigating patients 'and their families 'lives as they do with all other child and adolescent psychiatric problems. [The recently released National Guidelines

for Gender Dysphoria patients from Sweden and Finland do appear to be moving towards a much greater emphasis on alternative methods including psychosocial support, therapy, and long-term psycho-social evaluations — perhaps for years — prior to engaging in any "affirmation" medical interventions (hormones or surgery) See, e.g. "Finland Issues Strict Guidelines for Treating Gender Dysphoria" at https://genderreport.ca/finland-strict-guidelines-for-treating-gender-dysphoria/ ["Western countries around the world are *grappling with how to treat the exponentially growing number of children and adolescents being referred to gender clinics* for puberty blockers, cross-sex hormones and gender-affirming surgery. Finland recently issued very strict clinical guidelines for the treatment of children with gender dysphoria including: … clear differentiation in treatment guidelines between early-onset childhood gender dysphoria and adolescent-onset gender dysphoria…the guidelines acknowledge and recognize that identity exploration is a natural phase of adolescence and *restrict medical interventions* until "identity and personality development appear to be stable"….There is a *prioritization of psychotherapeutic non-invasive interventions* as the first course of action "due to variations in gender identity in minors"…. A *requirement* that there be *"no contraindications" prior to initiation of puberty blocker or cross-sex hormone interventions*… [such contraindications should include the presence of psychiatric illnesses such as depression, anxiety, or autistic conditions. Such disorders are reportedly present in over 50% of all gender discordant patients]…. and no surgical interventions are allowed for children underthe age of 18." ; See also, a Swedish National Investigative Report regarding cases of gender incongruence in children and young people, Article number 2021-3-7302 Published www.socialstyrelsen.se, March 2021. [Since our initial investigative report was published in 2015, the number of young people referred for investigation has *increased sharply, both in Sweden and internationally*. … *The reasons for the increase are not yet clear.*]

Such external pressures on providers should not be underestimated. Leaders in the field of gender dysphoria have been attacked, dissenters have been fired, and reputations have been sullied by activists who believe they know best how other people's children should be treated. The fact that science has not yet established the ideal treatment approaches to the diversity of situations does not seem to matter to these passionate persons.

19. Confirmation bias is a hazardous cognitive error that occurs throughout all of medicine and science. Confirmation bias is the methodologically defective tendency to process information by only looking for, and interpreting, evidence consistent with existing beliefs, favorite theories, and pre-conceived notions. This bias is a serious and potentially dangerous methodological error that leads a person or a field to ignore information that is contrary to what is common, fashionable, or has been taught to be the popular or "politically correct" theory of the day. It is often associated with a weak understanding of how science establishes the legitimacy of a therapy. Confirmation bias is often associated with the belief that because a therapeutic approach has been long employed or supported by powerful forces, adequate reliable-valid science must have previously established the popular approach. Both of the essential concepts of "gender affirmative treatment" and "conversion therapy" are based on such a misunderstanding.

20. The expected initial evaluation of a trans person typically begins with the patient who tells the evaluator, " "I am trans." The patient relates his or her symptoms of discomfort which may or may not fulfill DSM-5 criteria for Gender Dysphoria. Ideally a developmental history is taken from the parents and the patient to consider what is known as a differential diagnostic process to determine what other conditions may underlie these symptoms. The extent to which this latter process is undertaken depends upon the therapists *beliefs* about the origin of trans identities and the long term effectiveness of affirmative responses. To the extent that life-changing affirmative

distinctions. I attempt to summarize these three as though they are equally valid. I do not actually consider this to be true.

23. Gender dysphoria is conceptualized and described by some professionals and laypersons as though it were a serious, physical medical illness that causes suffering, comparable, for example, to prostate cancer, a disease that is curable before it spreads. Within this paradigm, whatever is causing distress associated with gender dysphoria—whether secondary sex characteristics such as facial hair, nose and jaw shape, presence or absence of breasts, or the primary anatomical sex organs of testes, ovaries, penis, or vagina—should be removed to alleviatethe illness. The promise of these interventions is the cure of the gender dysphoria. The underlyingassumption is that all types of gender dysphoria have their ultimate origin in "brain structures", often determined embryonically. Although numerous studies have been undertaken to attempt todemonstrate a distinctive physical "brain structure" associated with transgender identity, as of yetthere is no credible, reliable-valid scientific evidence that these patients have any defining abnormality in brain structure that precedes the onset of gender dysphoria. See, Mueller, De Cuypere & T'Sjoen. Transgender research in the 21st century: A selective critical review from a neurocognitive perspective. American Journal of Psychiatry 174: 12, 2017.

It should be noted that gender dysphoria is *a psychiatric rather than a medical diagnosis*. Since its inception in DSM-III, it has always and only been specified in the psychiatric DSM manuals. Notably, *gender dysphoria is the only psychiatric condition to be treated by surgery*, even though no endocrine or surgical intervention package corrects any identified biological abnormality (cf body integrity identity disorder (BIID) (See, Levine, *Reflections,* at 240.) In my opinion, the "affirmation" treatment protocols using endocrine and surgical "treatments" to change a psychiatric condition are not accepted by the relevant scientific community, are supported by

only "weak evidence" from methodologically defective research studies, and have no known, nor published error rates. Actual attempts at publishing error rates has come under the concept of "regrets" focused only only on patient injuries and misery following genital re-assignment surgery. There is much more to the human experience of trans patients regrets over time than the questionable, methodologically defective claims quoted by some of 2%. For example, in the Bränström., et.al., study, an enormous part of the sample was "lost" and never followed up. The authors failed to explore available data to see how many of these patients have de-transitioned, died via suicide, etc. One has to wonder why the suicide rate is reportedly so very high for patients who received trans genital surgery. In sum, these "treatments" remain experimental and poorly studied and we'll need much more and much higher quality scientific research before we will know if such "treatments" are actually helping or injuring patients. Is is essential to note that hormonal and surgical treatments for gender discordant patients have been increasingly done over a 50 year period and yet no reliable-valid protocols for evaluation or treatment have been properly researched, nor generally accepted by the relevant scientific community, nor published with methodologically sound error rates**.** For decades, vulnerable patients struggling with gender identity issues have deserved better, more effective, less experimental, less hazardous, less ideologically tainted, and properly researched treatments — they are still waiting.

24. Gender dysphoria can be effectively and alternatively conceptualized in developmental terms, as an adaptation to a psychological problem that was first manifested as a failure to establish a comfortable conventional sense of self in early childhood. This paradigm starts from the premise that all human lives are influenced by past processes and events. Trans lives are not exceptions to this axiom. (Levine, *Reflections*, at 238.) MHPs who think of gender dysphoria through this paradigm may work both to identify and address causes of the basic problem of the deeply

29. When a pre-adolescent child presents with gender dysphoria, a "watchful waiting" approach avoids hormonal treatments to allow for the developmental nature of gender identity in children to naturally resolve —that is, take its course from forces within and surrounding the child. Watchful waiting has two versions:

a. (Model 1 of watchful waiting) Treating any other psychological co-morbidities—that is, other mental illnesses as defined by the DSM-5—that the child may exhibit (separation anxiety, be bedwetting, attention deficit disorder, obsessive-compulsive disorder, depression) without a focus on gender

b. (Model 2 of watchful waiting) No treatment at all for anything, but a regular follow-up appointment. This might be labeled a "hands off" approach

The psychotherapy model: Alleviate distress by identifying and addressing causes

30. One of the foundational principles of psychotherapy has long been to work with a patient to identify the causes of observed psychological distress and then to address those causes as a means of alleviating the distress. The National Institute of Mental Health has promulgated the idea that 75% of adult psychopathology has its origins in childhood experience.

31. Many experienced practitioners in the field of gender dysphoria, including myself, have believed that it makes sense to employ these long-standing tools of psychotherapy for patients suffering gender dysphoria, asking the question as to what factors in the patient's life are the determinants of the patient's repudiation of his or her natal sex. (Levine, *Ethical Concerns*, at 8.) I and others have reported success in alleviating distress in this way for at least some patients, whether or not the patient's sense of discomfort or incongruence with his or her natal sex entirely disappeared. Relieving accompanying psychological co-morbidities leaves the patient freer to consider the pros and cons of transition as he or she matures.

is no sharp line between "watchful waiting" and the psychotherapy model in the case of prepubescent children.

35. To my knowledge, there is no credible, reliable-valid scientific evidence beyond anecdotal reports that psychotherapy can enable a return to male identification for genetically male boys, adolescents, and men, or return to female identification for genetically female girls, adolescents and women. *Controlled studies have never been attempted*. On the other hand, anecdotal case report evidence of such outcomes does exist; I and other clinicians have witnessed reinvestment in the patient's biological sex in some individual patients who are undergoing psychotherapy. The Internet contains many such reports, and I published a paper recently on a patient who sought my therapeutic assistance to reclaim his male gender identity after 30 years living as a woman and is in fact living as a man today. (Levine, *Transitioning*, at 1.) I have seen children desist even before puberty in response to thoughtful parental interactions and a few meetings of the child with a therapist. Recently, a paper reviewing the phenomenon of de-transition has been published in which the authors claims to have identified *60,000 case reports world wide* on the Internet. See Expósito-Campos P. A Typology of Gender Detransition and Its Implications for Healthcare Providers. J Sex Marital Ther. 2021;47(3):270-280. doi: 10.1080/0092623X.2020.1869126. Epub 2021 Jan 10. PMID: 33427094.

The affirmation therapy model

36. While it is widely agreed that the therapist should not directly challenge a claimed transgender identity in a child, some advocates and practitioners go much further, and promote and recommend that any expression of transgender identity should be immediately accepted as decisive, and thoroughly affirmed by means of consistent use of clothing, toys, pronouns, etc. associated with transgender identity. These advocates treat any question about the causes of the

a precondition for a diagnosis of gender dysphoria, precisely because of the risk of "transitory" symptoms and "hasty" diagnosis that might lead to "inappropriate" treatments. See, K. Zucker (2015), *The DSM-5 Diagnostic Criteria for Gender Dysphoria*, in C. Trombetta et al. (eds.), Management of Gender Dysphoria: Multidisciplinary Approach, DOI 10.1007/978-88-470-5696-1_4 (Springer-Verlag Italia 2015).

41. I do not know what proportion of practitioners are using which model. However, in my opinion, in the case of young children, prompt and thorough affirmation of a transgender identity disregards the principles of child development and family dynamics, and is not supported by credible, reliable-valid scientific evidence**.** Rather, the MHP must focus attention on the child's underlying internal and familial issues. Ongoing relationships between the MHP and the parents and the MHP and the child are vital to help the parents, child, other family members, and the MHP to understand over time the issues that need to be dealt with over time by each of them.

42. Likewise, since the child's sense of gender develops in interaction with his parents and their own gender roles and relationships, the responsible MHP will almost certainly need to delve into family and marital dynamics.

F. Patients Differ Widely and Must Be Considered Individually.

43. In my opinion, it is not possible to make a single, categorical statement about the proper treatment of children presenting with gender dysphoria or other gender-related issues. There is no single pathway of development and outcomes governing transgender identity, nor one that predominates over the large majority of cases. Instead, as individuals grow up and age, depending on their differing psychological, social, familial, and life experiences, their outcomes differ widely. I can, however, categorically opine that unproven, experimental affirmation "treatments"should not be used on uninformed or misinformed patients and families.

45. In almost any discussion of the diagnosis and care of patients suffering gender dysphoria or exhibiting transgender characteristics, the World Professional Association for Transgender Health (WPATH) and its Standards of Care will be mentioned. Accordingly, I provide some context concerning that private, activist, non-science, organization.

46. I was a member of the Harry Benjamin International Gender Dysphoria Association from 1974 until 2001. From 1997 through 1998, I served as the Chairman of the eight-person International Standards of Care Committee that issued the fifth version of the Standards of Care. I resigned my membership in 2002 due to my regretful conclusion that the organization and its recommendations had become dominated by politics and ideology, rather than by proper, reliable scientific methodologies, as was its mission years earlier. In approximately 2007, the Henry Benjamin International Gender Dysphoria Association changed its name to the World Professional Association for Transgender Health.

47. WPATH is a voluntary membership, activist advocacy organization. Since at least 2002, attendance at its biennial meetings has been open to trans individuals who are *not licensed professionals*. While this ensures taking patients 'perceived needs, values, and sensibilities into consideration, it limits the ability for honest, methodologically competent scientific debate. It also means that WPATH can no longer be considered a purely professional or scientific organization.

48. WPATH takes a very narrow and politically-ideologically driven view on increasingly controversial issues as to which there is a wide range of opinion among professionals. WPATH explicitly views itself as not merely a scientific organization, but also as an advocacy organization. *These are, obviously, conflicted, incompatible, and contradictory goals*. (Levine, *Reflections*, at 240.) WPATH is supportive to those who want Sex Reassignment Surgery ("SRS") even though such surgery is *not supported by credible, reliable-valid scientific research*, not accepted by the

relevant scientific community, and has no known error rates, and no careful systematic follow-up using agreed upon criteria to even assess multifaceted failure rates. Skepticism as to the benefits of SRS to patients, and strong alternate views, are not well tolerated in discussions within the organization. Such views have been literally shouted down and effectively silenced by the large numbers of nonprofessional adults who attend the organization's biennial meetings. Such "mob rule" is quite incompatible with appropriate, competent methodological discussions.

49. The Standards of Care ("SOC") is the product of an enormous effort, but it is not a politically neutral document. WPATH aspires to be both a scientific organization and an advocacy group for the transgendered. These aspirations are clearly in sharp conflict. The most serious limitations and defects of the Standards of Care, however, are not primarily political. They are caused by the decades-long and continuing lack of credible, rigorous research in the field, which allows room for passionate convictions and ongoing controversies on how to care for the transgendered. See, e.g. Vrouenraets et al, *Early Medical Treatment of Children and Adolescents With Gender Dysphoria: An Empirical Ethical Study,* Journal of Adolescent Health 57 (2015) 367e373. [The Endocrine Society and the World Professional Association for Transgender Health published guidelines for the treatment of adolescents with gender dysphoria (GD). The guidelines recommend the use of gonadotropin-releasing hormone agonists in adolescence to suppress puberty. However, in actual practice, *no consensus exists whether to use these early medical interventions* … Conclusions: As long as *debate* remains on these seven themes and *onlylimited long-term data are available*, *there will be no consensus on treatment*. Therefore, more systematic interdisciplinary and (worldwide) multi-center research is required.]

50. In recent years, WPATH has fully adopted — in the absence of reliable-valid scientific research — some mix of the medical and civil rights paradigms. It has downgraded the role of

"the cross gender wishes usually fade over time and do not persist into adulthood, with only 2.2% to 11.9% continuing to experience gender discordance." A third summarized the existing data as showing that "Symptoms of GID at prepubertal ages decrease or disappear in a considerable percentage of children (estimates range from 80-95%)." A 2021 publication found that 12% of previously evaluated grade school aged children persisted in their trans identities many years later. (Singh, Bradley, and Zucker, Frontiers of Psychiatry. See, P. T. Cohen-Kettenis, H. A. Delemarre-van de Waal et al. (2008), *The Treatment of Adolescent Transsexuals: Changing Insights*, J. Sexual Medicine 5(8) 1892 at 1895.

55. It is not yet known how to distinguish those children who will desist from that small minority whose trans identity will persist. (Zucker, Gender Dysphoria in Children and Adolescents, in Principles and Practices of Sex Therapy 6th edition, Guilford Press, 2020; Levine, *Ethical Concerns*, at 9.) Even severity of gender dysphoria is not a strong predictor of persistence. It is also apparent in the adolescent phenomenon of rapid onset of gender dysphoria following a gender normative childhood that childhood gender identity is not inherently stable. Some of these individuals desist and others evolve dramatically to become more non-binary and accepting of their complex male and female identifications.

56. Desistance (a patients' willing reacceptance of their biological sex through normal developmental processes) within a relatively short period may also be a common outcome for post-pubertal youths who exhibit recently described "rapid onset gender disorder." I observe an increasingly vocal online community of young women who have reclaimed a female identity after claiming a male gender identity at some point during their teen years. However, reliable-valid scientific data on outcomes for this age group with and without therapeutic interventions is not yet available. A recent review of de-transitioning claimed to have identified 60,000 case histories in

a search of proliferating websites devoted to this topic (Pablo Exposito-Campos. A typology of gender detransition and its implications for health care providers J Sex & Marital Therapy 2020 https:..doi.org/101080/0092623x.2020.1869126). In the past WPATH has simply declined to discuss this vital topic, another example of WPATH's political consensus-seeking, *increasingly anti-science methodology*.

57. In contrast, there is now data that suggests that a therapy that encourages social transition dramatically changes outcomes and often "locks in" a patient's journey into a life course of dependence on experimental hormone "treatments". A prominent group of authors has written that "The gender identity affirmed during puberty appears to predict the gender identity that will persist into adulthood." Similarly, a comparison of recent and older studies suggests that when an "affirming" methodology is used with young children, a substantial proportion of children who would otherwise have desisted by adolescence—that is, achieved comfort identifying with their natal sex—instead persist in a transgender identity. (Zucker, *Myth of Persistence*, at 7.)18

58. Indeed, a review of multiple studies of boys treated for gender dysphoria across the last three decades found that early social transition to living as the opposite sex severely reduces the likelihood that the child will revert to identifying with the child's natal sex, Studies that began before the widespread use of social transition for young children reported desistance rates in the range of 80-98%. A more recent study reported that fewer than 20% of boys who engaged in a partial or complete transition prior to puberty desisted when surveyed at age 15. See (T.D. Steensma, J.K. McGuire et al. (2013), *Factors Associated with Desistance & Persistence of Childhood Gender Dysphoria: A Qualitative Follow-up Study*, J. of the Am. Academy of Child and Adolescent Psychiatry. 52, 582. ; See, C. Guss et al. (2015), Transgender and Gender

population, or to the notably worse outcomes exhibited by the transgender population generally. *See, e.g.,* B. Ehrensaft (2015), *Listening and Learning from Gender-Nonconforming Children,* The Psychoanalytic Study of the Child 68(1) 28 at 34: "In my own clinical practice . . . of those children who are carefully assessed as transgender and who are allowed to transition to their affirmed gender, we have no documentation of a child who has 'desisted 'and asked to returnto his or her assigned gender."

61. However, I agree with Zucker who has written, "…we cannot rule out the possibility that early successful treatment of childhood GID [Gender Identity Disorder] will diminish the role of a continuation of GID into adulthood. If so, successful treatment would also reduce the need for the long and difficult process of sex reassignment which includes hormonal and surgical procedures with substantial medical risks and complications." See, Zucker, *Myth of Persistence*,at 8 (citing H. Meyer-Bahlburg (2002), *Gender Identity Disorder in Young Boys: A Parent- & Peer-Based Treatment Protocol*, Clinical Child Psychology & Psychiatry 7, 360 at 362.).

By the same token, a therapeutic methodology for children that *increases* the likelihood that the child will continue to identify as the opposite gender into adulthood will *increase* the need for the long and potentially problematic processes of hormonal and genital and cosmetic surgical procedures.

62. Given these facts, *encouraging social transition in children remains controversial*. Supporters of such transition acknowledge that "Controversies among providers in the mental health and medical fields are abundant . . . These include differing assumptions regarding . . . the age at which children . . . should be encouraged or permitted to socially transition These are complex and providers in the field continue to be at odds in their efforts to work in the best interests of the youth they serve." See, A. Tishelman et al. (2015), *Serving Transgender Youth: Challenges,*

Dilemmas and Clinical Examples, Prof. Psychol. Res. PR. at 11, DOI: 10.1037/a0037490 ("*Serving TG Youth*") Transition then, should be undertaken only subject to standards, protocols, and reviews appropriate to actual clincial experiments [Clincial experiments involve time-honored careful processes with Institutional Review Board — human subjects protections — approval required, a predetermined method of evaluation, primary and secondary endpoints and safeguards to protect the rights of patients to truly informed consent. These protections are not present in the Transgender Treatment Industry when vulnerable patients are receving "treatments" that lack sufficient proof of efficacy and safety.]

63. In sum, therapy for young children that encourages transition cannot be considered to be neutral, but instead *is an experimental procedure* that has a high likelihood of changing the life path of the child, with highly unpredictable effects on mental and physical health, suicidality, and life expectancy. Claims that a civil right is at stake do not change the fact that what is proposed is a social and medical experiment on vulnerable patients. (Levine, *Reflections,* at 241.)

IV. THE AVAILABLE DATA DOES NOT SUPPORT THE CONTENTION THAT "AFFIRMATION" OF TRANSGENDER IDENTITY REDUCES SUICIDE OR RESULTS IN BETTER PHYSICAL OR MENTAL HEALTH OUTCOMES GENERALLY.

64. I am aware that organizations including The Academy of Pediatrics and Parents, Families and Friends of Lesbians and Gays (PFLAG)) have published statements that suggest that all children who express a desire for a transgender identity should be promptly supported in that claimed identity. This position appears to rest on the belief —which is widely promulgated by certain advocacy organizations—that science has already established that prompt "affirmance" is best for all patients, including all children, who present indicia of transgender identity. As I discuss later below, this belief is scientifically incorrect, and ignores both what is known and what is unknown.

65. It is instructive to consider how policies are constructed by professional and lay organizations. Professional association vote on policies that are formulated in small committees. Such consensus processes are not a reliable valid scientific methodology. These professional, political, or community support groups do not rely upon scientifically tested methodologies, although they claim to have done so. All methodologically informed workers, even among those who work in this arena, have in the past and continue to conclude that there is low level science underlying treatment patterns and the policies that encourage them. A "low" level is defined by specific criteria of validity or trustworthiness.

Professional associations have a tainted history of supporting unproven, controversial notions that were later shown to be improper, unreliable, and/or unethical. For example, the American Medical Association supported eugenic proposals to "improve the quality of the human stock" by coercive sterilization of "defective and undesirable Americans" and selective breeding. During the 1890s the renowned surgeon Albert Ochsner was invited to speak about his vasectomy procedure to the meeting of the American Medical Association. He recommended vasectomies to prevent the reproduction of "criminals, chronic inebriates, imbeciles, perverts, and paupers." (See, Oshsner, AJ, Surgical treatment of habitual criminals. JAMA, 1899:32:867-868). The AMA's support was a political not a scientific process.

Similarly, the American Breeders Association founded a Eugenics Record Office with an advisory board that included a Harvard physiologist, a Princeton psychiatrist, a University of Chicago economist, and a Rockefeller Institute for Medical Research recipient of the Nobel Prize in Medicine. This movement was focused on "terminating the bloodlines" of the "submerged lower ten percent of the population with 'defective germ-plasm'". (See, Black, E. War Against the Weak, New York, NY, 2003).

such multi-disciplinary research, analysis, and treatment is now being blocked and threatened as "conversion therapy" by political advocates. [See, Olson-Kennedy, J, Cohen-Kettenis, P., et al., Research priorities for gender nonconforming/transgender youth gender identity development and biopsychosocial outcomes, Current Opinion in Endocrinology & Diabetes and Obesity: April 2016 - Volume 23 - Issue 2 - p 172-179, doi: 10.1097/MED.0000000000000236]

Suicide, suicidal ideation, suicide attempts, suicidal manipulations

74. With respect to suicide risks, individuals with gender dysphoria are well known to have a higher risk of committing suicide or otherwise suffering increased mortality before and after not only social transition, but also before and after SRS. (Levine*, Reflections,* at 242.) For example, in the United States, the death rates of trans veterans are *comparable to those with schizophrenia and bipolar diagnoses but 20 years earlier* than expected. These crude death rates include significantly elevated suicide rates. (Levine, *Ethical Concerns,* at 10.) Similarly, researchers in Sweden and Denmark have reported on almost all individuals who underwent sex-reassignment surgery over a 30-year period. The Swedish follow-up study found a suicide rate in the post-Sex Reassignment Surgery (SRS) population *19.1 times greater than that of the controls after affirmation treatment*; both studies demonstrated elevated mortality rates from *medical and psychiatric conditions*. (Levine, *Ethical Concerns,* at 10.) See, C. Dhejne et al. (2011), Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden, PLOS ONE 6(2) e16885 ("Long Term"); R. K. Simonsen et al. (2016), Long-Term Follow-Up of Individuals Undergoing Sex Reassignment Surgery: Psychiatric Morbidity & Mortality, Nordic J. of Psychiatry 70(4).

75. Advocates of immediate and unquestioning affirmation of social transition in children who indicate a desire for a transgender identity sometimes assert that any other course will result

79. Thus, given the lack of credible science evidence for suicide reduction, transition of any sort must be justified, if at all, as a life-*enhancing* measure, not a lifesaving measure — although there is no credible to support either hypothesis. (Levine, *Reflections,* at 242.) In my opinion, this is an important fact that patients, parents, and even many MHPs fail to understand. They also often do not understand that the current gender affirmation "treatment" datafor life saving or enhancement are so weak, sparse, and poorly gathered that they do not permit usto know if gender affirmation interventions will increase or decrease a patient's risk of suicide orreduced depression ***or even an improved life.*** How many years will go by before such research is competently completed? See, C. Dragon, P. Guerino, et al. (2017), *Transgender Medicare Beneficiaries & Chronic Conditions: Exploring Fee-for-Service Claims Data*, LGBT Health 4(6) 404, DOI: 10.1089/lgbt.2016.0208.

V. KNOWN, LIKELY, OR POSSIBLE DOWNSIDE RISKS ATTENDANT ON MOVING QUICKLY TO "AFFIRM" TRANSGENDER IDENTITY IN CHILDREN.

80. As some research has already demonstrated, enabling and affirming social transition in a prepubescent child appears to be highly likely to increase the odds that the child will in time pursue pubertal suppression and persist in a transgender identity into adulthood. I consider the ethical implications of this intervention in the next section. Here, I emphasize that the Mental Health Professional (MHP), pediatrician, and parent must consider long-term as well as short - term implications of life as a transgender individual when deciding whether to permit or encourage a child to socially transition.

81. The multiple studies from different nations that have documented ***the increased vulnerability of the adult transgender population to substance abuse, mood and anxiety disorders, suicidal ideation, and other health problems stand as a warning***: Given these well-documented data, ***assisting a child down the road to becoming a transgender adult is an ominous***

decision. Data about trans adults remind all concerned that a casual assumption that transition will improve the child's life is ***not*** justified beyond his or her short term happiness about gender expression. The possibility that steps along this pathway, while lessening the relatively minor pain of gender dysphoria, *could lead to additional future sources of crippling emotional and psychological pain*, are too often not properly considered by advocates of social transition and not considered at all by the trans child. (Levine, *Reflections,* at 243.). The informed consent process for parents considering this option ethically should spell out short-term gains and long-term risks (beginning at early puberty risks). What follows is a discussion of the medical, social, and psychological risks of affirmation interventions ("transition").

A. Physical risks associated with transition

82. Sterilization. Sex Reassignment Surgery (SRS) that removes testes, ovaries, or the uterus is ***inevitably sterilizing and irreversible***. While by no means all transgender adults elect SRS, many patients do ultimately feel compelled to take this serious step in their effort to "live fully as the opposite sex". More immediately, practitioners recognize that the administration of cross-sex hormones, which is often viewed as a less radical measure, and is now increasingly done to minors, creates a risk of irreversible sterility. These risks have never been properly studied nor quantified in a systematic manner. As a result, even when treating a child, the MHP, patient, and parents must consider ***permanent loss of reproductive capacity (sterilization)*** *to be one of the major risks of starting down the road*. The risk that supporting social transition may put the child on a pathway that leads to intentional or unintentional permanent sterilization is particularly concerning given ***the disproportionate representation of minority and other vulnerable groups*** among children reporting a transgender or gender-nonconforming identity. *See* C. Guss etal., *TGN Adolescent Care* at 4 ("a side effect [of cross-sex hormones] may be infertility") and 5

98. I noted above an increasingly visible online community of young women who have desisted after claiming a male gender identity at some point during their teen years. Given the rapid increase in the number of girls presenting to gender clinics within the last few years, the phenomena of regret and desistance by young women deserves careful attention and study by MHPs. As reported by one author in 2021, *60,000 testimonies of personal de-transition can be found on the Internet*. See, Pablo Exposito-Campos. A typology of gender detransition and its implications for health care providers J Sex & Marital Therapy 2020 https:..doi.org/101080/0092623x.2020.1869126).

99. Thus, misleading reports of clinical experience, publications that misreport evidence, and the unregulated content of the Internet - many falsely claiming transitions are "easily reversible" — prevent the sobering acceptance of what has previously been asserted for decades — for most all such patients "once a transgendered person, always a transgendered person", whether referring to a child, adolescent, or adult, male or female.

VI. MEDICAL ETHICS & INFORMED CONSENT

A. The obligation of the mental health professional to enable and obtain informed consent

100. I have reviewed above the knowledge and experience that, in my view, a mental health professional should have before undertaking the responsibility to counsel or treat a child who is experiencing gender dysphoria or transgender identification. The MHP who undertakes this type of responsibility must also be guided by the ethical principles that apply to all health care professionals. One of the oldest and most fundamental principles guiding medical and psychological care—part of the Hippocratic Oath—is that the physician must "do no harm." This states an ethical responsibility that cannot be delegated to the patient. Physicians themselves must

119. In light of the profound uncertainties in the field, and the many highly predictable or probable lifetime costs to the child if he or she persists in a transgender identity into adulthood, in my opinion it is not consistent with principles of medical ethics for physicians or other MHPs to suggest that parents should not or have no right to explore possible therapeutic options to assist their child to achieve comfort with the gender corresponding to his or her sex. The use of the label "reparative therapy" or "conversion therapy" by some advocates to lump all such possible therapies together and disparage them does not change this equation. (Levine, *Informed Consent,* at 7.)

120. The transgender clinical arena is growing increasingly uncertain as more attention has been paid to the lack of fundamental studies to support the current widespread fashions of professional recommendations and confirmation bias has been identified in recent highly acclaimed but deeply flawed work. While the general public is now accustomed to reading about trans culture wars, my opinion is that of a clinician who respects scientific methods of ascertaining best treatments. More caution is indicated when the consequences are greater. It has been repeatedly demonstrated in medicine that one size does not fit all. One must reject the idea that if a young person is trans, nothing else matters—the treatment should be immediate affirmation and endocrine support. All must realize that 50 years after trans treatment began to spread across the world, despite more than 10,000 publications, it is not known whether the burgeoning Transgender Treatment Industry is helping or damaging most GD patients.

121. It is my opinion that the scientific community finds the following matters to be uncertain, controversial, or incorrect.

— Gender dysphoria is a serious, physical brain based medical illness that causes suffering that must be treated by hormones and surgery if patients seek such treatments.

— All patients who label themselves as transgendered, regardless of the >120 sub-labels that may be invoked, gender all should be offered the same physical body-changing treatments, if they so desire.

— Hormones and surgery improve the lives of the transgendered in the long run.

— "Above all do no harm" principle can be sidestepped when administering hormones and removing healthy breast and genital tissues in the case of trans persons because it is "medically necessary" –that is, these patients represent a special exception to 2500 years of medical ethics.

-The uncertain long-term adjustments of trans adults, the rates of detransition, disappointment, and chronic depressive, anxiety, and substance abuse disorders do not need to be calculated nor should what is known about high psychiatric morbidity following hormonal and/or surgical treatment should not slow the affirmative treatment policy of trans youth.

--Civil rights considerations are more important than unanswered relevant scientific questions.

XX. SUMMARY OPINIONS:

122. There are no long-term, peer-reviewed published, credible, reliable and valid, research studies documenting or establishing:

a. The percentage of patients receiving gender transition procedures who are helped by such procedures according to well known criteria.

b. The percentage of patients receiving gender transition procedures who are harmed by such procedures according to well known criteria.

c. The reliability and validity of assessing gender identity by relying solely upon the expressed desires of a patient.

d. The mental health outcomes of trans behaving children who are either affirmed or not affirmed in childhood.

e. The percentage of various types of childhood functional challenges and psychiatric diagnoses of trans identified children

f. The percentage of patients whose new trans identity has been created by involvement in social media.

123. The above list of six issues can stimulate new research whose results may shape future trans care. In the meantime, those with gender dysphoria or a trans identity have a right to be more fully informed about what is known as do their physicians. Physicians, psychologists, parents, and patients have a right to be *protected* from these current experimental, politically tainted, fashionable "treatments".

124. Informed consent is designed to protect the rights of patients and families, the cognitive and ethical processes of physicians, and the ethical and legal duties of health care institutions. The need for credible, reliable-valid science is also essential to protect each of these entities. The informed consent document for affirmative treatments of youth should specify that up to 88% of children without affirmation will desist (heal naturally without treatment) from their childhood- onset trans preoccupations. Physicians always need to know the patient's original sex because while gender identity can dramatically change, biological sex and its unique susceptibilities to disease does not.

125. The Transgender Treatment Industry's policies and advocacies are a niche group of well meaning mental health professionals, endocrinologists, plastic and urological surgeons, and transgendered individuals. Many in their individual professions have differing opinions. They should not be viewed as speaking for all of medicine on these highly controversial issues.

126. Science not politics needs to drive trans care. The medical professions has many tragic examples of when political sensibilities drive medical treatments. When policy is made by voting in the face of low quality science, claims that treatments are evidence-based should be considered misleading and deceptive.

127. No medical, surgical, or psychiatric treatment is invariably successful in producing an agreed upon outcome. In other branches of medicine and psychiatry risks and benefits, outcomes and error rates are better known, far less controversial, and much better proven by credible, reliable-valid scientific research. Error rates for gender affirmation diagnoses, errors rates for predictions of effective vs. harmful affirmation treatments, error rates for increases or decreases in suicidal risk following affirmation treatments, remain unknown. In the field of gender affirmation intervention there has been a rush to treat and a remarkable absence of ethical concern based on obvious scientific limitations as outlined in this report.

128. **Expert Witness Report Methodological Limitations**: My opinions and hypotheses in this matter are — as in all expert witness reports — subject to the limitations of documentary and related evidence, the impossibility of absolute predictions, as well as the limitations of social, biological, and medical science. I have not met with, nor personally interviewed, anyone in this case. As always, I have no expert opinions regarding the veracity of witnesses in this case. I have not yet reviewed all of the evidence in this case and my opinions are subject to change at any time as new information becomes available to me. Only the trier of fact can determine the credibility of witnesses and how scientific research may or may not be related to the specific facts of any particular case. In my opinion, a key role of an expert witness is to help the court, lawyers, parties, and the public understand and apply reliable scientific, technical, and investigative principles, hypotheses, methods, and information. I have transmitted this confidential expert report directly

S1 Biopharma - a phase 1-B non-blinded study of safety, tolerability and efficacy of Lorexys in premenopausal women with HSDD

HRA - qualitative and cognitive interview study for men experiencing PE

Publications

A) Books

1) Pariser SR, Levine SB, McDowell M (eds.), Clinical Sexuality, Marcel Dekker, New York, 1985
2) Sex Is Not Simple, Ohio Psychological Publishing Company, 1988; Reissued in paperback as: Solving Common Sexual Problems: Toward a Problem Free Sexual Life, Jason Aronson, Livingston, NJ. 1997
3) Sexual Life: A Clinician's Guide. Plenum Publishing Corporation. New York, 1992
4) Sexuality in Midlife. Plenum Publishing Corporation. New York, 1998
5) Editor. Clinical Sexuality. Psychiatric Clinics of North America, March, 1995.
6) Editor, (Candace Risen and Stanley Althof, associate editors) Handbook of Clinical Sexuality for Mental Health Professionals. Routledge, New York, 2003
   (a) 2006 SSTAR Book Award: Exceptional Merit
7) Demystifying Love: Plain Talk For The Mental Health Professional. Routledge, New York, 2006
8) Senior editor, (Candace B. Risen and Stanley E. Althof, Associate editors), Handbook of Clinical Sexuality for Mental Health Professionals. 2nd edition Routledge, New York, 2010. See review by Pega Ren, JSex&Marital Therapy
9) Barriers to Loving: A Clinician's Perspective. Routledge, New York, 2014.
10) Senior editor Candace B. Risen and Stanley E. Althof, Associate editors), Handbook of Clinical Sexuality for Mental Health Professionals. 3rd edition Routledge, New York, 2016

B) Research and Invited Papers

(When his name is not listed in a citation, Dr. Levine is either the solo or the senior author)

1) Sampliner R. Parotid enlargement in Pima Indians. Annals of Internal Medicine 1970; 73:571-73
2) Confrontation and residency activism: A technique for assisting residency change: World Journal of Psychosynthesis 1974; 6: 23-26
3) Activism and confrontation: A technique to spur reform. Resident and Intern Consultant 173; 2
4) Medicine and Sexuality. Case Western Reserve Medical Alumni Bulletin 1974:37:9-11.

5) Some thoughts on the pathogenesis of premature ejaculation. J. Sex & Marital Therapy 1975; 1:326-334

6) Marital Sexual Dysfunction: Introductory Concepts. Annals of Internal Medicine 1976;84:448-453

7) Marital Sexual Dysfunction: Ejaculation Disturbances 1976; 84:575-579

8) Yost MA: Frequency of female sexual dysfunction in a gynecology clinic: An epidemiological approach. Archives of Sexual Behavior 1976;5:229-238

9) Engel IM, Resnick PJ, Levine SB: Use of programmed patients and videotape in teaching medical students to take a sexual history. Journal of Medical Education 1976;51:425-427

10) Marital Sexual Dysfunction: Erectile dysfunction. Annals of Internal Medicine 1976;85:342-350

11) Articles in Medical Aspects of Human Sexuality

    (a) Treating the single impotent male. 1976; 10:123, 137

    (b) Do men enjoy being caressed during foreplay as much as women do? 1977; 11:9

    (c) Do men like women to be sexually assertive? 1977;11:44

    (d) Absence of sexual desire in women: Do some women never experience sexual desire? Is this possibility genetically determined? 1977; 11:31

    (e) Barriers to the attainment of ejaculatory control. 1979; 13:32-56.

    (f) Commentary on sexual revenge.1979;13:19-21

    (g) Prosthesis for psychogenic impotence? 1979;13:7

    (h) Habits that infuriate mates. 1980;14:8-19

    (i) Greenberger-Englander, Levine SB. Is an enema an erotic equivalent?1981; 15:116

    (j) Ford AB, Levine SB. Sexual Behavior and the Chronically Ill Patients. 1982; 16:138-150

    (k) Preoccupation with wife's sexual behavior in previous marriage 1982; 16:172

    (l) Co-existing organic and psychological impotence. 1985;19:187-8

    (m) Althof SE, Turner LA, Kursh ED, Bodner D, Resnick MI, Risen CB. Benefits and Problems with Intracavernosal injections for the treatment of impotence. 1989;23(4):38-40

12) Male Sexual Problems. Resident and Staff Physician 1981:2:90-5

13) Female Sexual Problems. Resident and Staff Physician 1981:3:79-92

14) How can I determine whether a recent depression in a 40 year old married man is due to organic loss of erectile function or whether the depression is the source of the

dysfunction? Sexual Medicine Today 1977;1:13

15) Corradi RB, Resnick PJ Levine SB, Gold F. For chronic psychologic impotence: sex therapy or psychotherapy? I & II Roche Reports; 1977

16) Marital Sexual Dysfunction: Female dysfunctions 1977; 86:588-597

17) Current problems in the diagnosis and treatment of psychogenic impotence. Journal of Sex & Marital Therapy 1977; 3:177-186

18) Resnick PJ, Engel IM. Sexuality curriculum for gynecology residents. Journal of Medical Education 1978; 53:510-15

19) Agle DP. Effectiveness of sex therapy for chronic secondary psychological impotence Journal of Sex & Marital Therapy 1978; 4:235-258

20) DePalma RG, Levine SB, Feldman S. Preservation of erectile function after aortoiliac reconstruction. Archives of Surgery 1978; 113-958-962

21) Conceptual suggestions for outcome research in sex therapy Journal of Sex & Marital Therapy 1981; 6:102-108

22) Lothstein LM. Transsexualism or the gender dysphoria syndrome. Journal of Sex & Marital Therapy 1982; 7:85-113

23) Lothstein LM, Levine SB. Expressive psychotherapy with gender dysphoria patients Archives General Psychiatry 1981; 38:924-929

24) Stern RG Sexual function in cystic fibrosis. Chest 1982; 81:422-8

25) Shumaker R. Increasingly Ruth: Towards understanding sex reassignment surgery Archives of Sexual Behavior 1983; 12:247-61

26) Psychiatric diagnosis of patients requesting sex reassignment surgery. Journal of Sex & Marital Therapy 1980; 6:164-173

27) Problem solving in sexual medicine I. British Journal of Sexual Medicine 1982; 9:21-28

28) A modern perspective on nymphomania. Journal of Sex & Marital Therapy 1982; 8:316-324

29) Nymphomania. Female Patient 1982;7:47-54

30) Commentary on Beverly Mead's article: When your patient fears impotence. Patient Care 1982; 16:135-9

31) Relation of sexual problems to sexual enlightenment. Physician and Patient 1983 2:62

32) Clinical overview of impotence. Physician and Patient 1983; 8:52-55.

33) An analytical approach to problem-solving in sexual medicine: a clinical introduction to the psychological sexual dysfunctions. II. British Journal of Sexual Medicine

34) Coffman CB, Levine SB, Althof SE, Stern RG Sexual Adaptation among single young adults with cystic fibrosis. Chest 1984; 86:412-418

35) Althof SE, Coffman CB, Levine SB. The effects of coronary bypass in female sexual, psychological, and vocational adaptation. Journal of Sex & Marital Therapy 1984; 10:176-184

36) Letter to the editor: Follow-up on Increasingly Ruth. Archives of Sexual Behavior 1984; 13:287-9

37) Essay on the nature of sexual desire Journal of Sex & Marital Therapy 1984; 10:83-96

38) Introduction to the sexual consequences of hemophilia. Scandanavian Journal of Haemology 1984; 33:(supplement 40).75-

39) Agle DP, Heine P. Hemophila and Acquired Immune Deficiency Syndrome: Intimacy and Sexual Behavior. National Hemophilia Foundation; July, 1985

40) Turner LA, Althof SE, Levine SB, Bodner DR, Kursh ED, Resnick MI. External vacuum devices in the treatment of erectile dysfunction: a one-year study of sexual and psychosocial impact. Journal of Sex & Marital Therapy

41) Schein M, Zyzanski SJ, Levine SB, Medalie JH, Dickman RL, Alemagno SA. The frequency of sexual problems among family practice patients. Family Practice Research Journal 1988; 7:122-134

42) More on the nature of sexual desire. Journal of Sex & Marital Therapy 1987; 13:35-44

43) Waltz G, Risen CB, Levine SB. Antiandrogen treatment of male sex offenders. Health Matrix 1987; V.51-55.

44) Lets talk about sex. National Hemophilia Foundation January, 1988

45) Sexuality, Intimacy, and Hemophilia: questions and answers . National Hemophilia Foundation January, 1988

46) Prevalence of sexual problems. Journal Clinical Practice in Sexuality 1988;4:14-16.

47) Kursh E, Bodner D, Resnick MI, Althof SE, Turner L, Risen CB, Levine SB. Injection Therapy for Impotence. Urologic Clinics of North America 1988; 15(4):625-630

48) Bradley SJ, Blanchard R, Coates S, Green R, Levine S, Meyer-Bahlburg H, Pauly I, Zucker KJ. Interim report of the DSM-IV Subcommittee for Gender Identity Disorders. Archives of Sexual Behavior 1991;;20(4):333-43.

49) Sexual passion in mid-life. Journal of Clinical Practice in Sexuality 1991 6(8):13-19

50) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DR, Resnick MI. Intracavernosal injections in the treatment of impotence: A prospective study of sexual, psychological, and marital functioning. Journal of Sex & Marital Therapy 1987**;** 13:155-167

51) Althof SE, Turner LA, Risen CB, Bodner DR, Kursh ED, Resnick MI. Side effects of self-administration of intracavernosal injection of papaverine and phentolamine for treatment of impotence. Journal of Urology 1989; 141:54-7

52) Turner LA, Froman SL, Althof SE, Levine SB, Tobias TR, Kursh ED, Bodner DR. Intracavernous injection in the management of diabetic impotence. Journal of Sexual Education and Therapy 16(2):126-36, 1989

53) Is it time for sexual mental health centers? Journal of Sex & Marital Therapy 1989**;**

54) Althof SE, Turner LA, Levine SB, Risen CB, Bodner D, Kursh ED, Resnick MI. Sexual, psychological, and marital impact of self injection of papaverine and phentolamine: a long-term prospective study. Journal of Sex & Marital Therapy

55) Althof SE, Turner LA, Levine SB, Risen CB, Bodner D, Kursh ED, Resnick MI. Why do so many men drop out of intracavernosal treatment? Journal of Sex & Marital Therapy. 1989; 15:121-9

56) Turner LA, Althof SE, Levine SB, Risen CB, Bodner D, Kursh ED, Resnick MI. Self injection of papaverine and phentolamine in the treatment of psychogenic impotence. Journal of Sex & Marital Therapy. 1989; 15(3):163-78

57) Turner LA, Althof SE, Levine SB, Risen CB, Bodner D, Kursh ED, Resnick MI. Treating erectile dysfunction with external vacuum devices: impact upon sexual, psychological, and marital functioning. Journal of Urology 1990; 141(1):79-82

58) Risen CB, Althof SE. An essay on the diagnosis and nature of paraphilia Journal of Sex & Marital Therapy 1990; 16(2):89-102.

59) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DB, Kursh ED, Resnick MI. Through the eyes of women: the sexual and psychological responses of women to their partners' treatment with self-injection or vacuum constriction therapy. International Journal of Impotence Research (supplement 2)1990; 346-7.

60) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DB, Kursh ED, Resnick MI. A comparison of the effectiveness of two treatments for erectile dysfunction: self injection vs. external vacuum devices. . International Journal of Impotence Research (supplement 2)1990; 289-90

61) Kursh E, Turner L, Bodner D, Althof S, Levine S. A prospective study on the use of the vacuum pump for the treatment of impotence.International Journal of Impotence Research (supplement 2)1990; 340-1.

62) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DB, Kursh ED, Resnick MI. Long term use of intracavernous therapy in the treatment of erectile dysfunction in Journal of Sex & Marital Therapy 1991; 17(2):101-112

63) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DB, Kursh ED, Resnick MI. Long term use of vacuum pump devices in the treatment of erectile dsyfunction in Journal of Sex & Marital Therapy 1991;17(2):81-93

64) Turner LA, Althof SE, Levine SB, Bodner DB, Kursh ED, Resnick MI. A 12-month

comparison of the effectiveness of two treatments for erectile dysfunction: self injection vs. external vacuum devices. Urology 1992;39(2):139-44

65) Althof SE, The pathogenesis of psychogenic impotence. J. Sex Education and Therapy. 1991; 17(4):251-66

66) Mehta P, Bedell WH, Cumming W, Bussing R, Warner R, Levine SB. Letter to the editor. Reflections on hemophilia camp. Clinical Pediatrics 1991; 30(4):259-260

67) Successful Sexuality. Belonging/Hemophilia. (Caremark Therapeutic Services), Autumn, 1991

68) Psychological intimacy. Journal of Sex & Marital Therapy 1991; 17(4):259-68

69) Male sexual problems and the general physician, Georgia State Medical Journal 1992; 81(5): 211-6

70) Althof SE, Turner LA, Levine SB, Bodner DB, Kursh E, Resnick MI. Through the eyes of women: The sexual and psychological responses of women to their partner's treatment with self-injection or vacuum constriction devices. Journal of Urology 1992; 147(4):1024-7

71) Curry SL, Levine SB, Jones PK, Kurit DM. Medical and Psychosocial predictors of sexual outcome among women with systemic lupus erythematosis. Arthritis Care and Research 1993; 6:23-30

72) Althof SE, Levine SB. Clinical approach to sexuality of patients with spinal cord injury. Urological Clinics of North America 1993; 20(3):527-34

73) Gender-disturbed males. Journal of Sex & Marital Therapy 19(2):131-141, 1993

74) Curry SL, Levine SB, Jones PK, Kurit DM. The impact of systemic lupus erythematosis on women's sexual functioning. Journal of Rheumatology 1994; 21(12):2254-60

75) Althof SE, Levine SB, Corty E, Risen CB, Stern EB, Kurit D. Clomipramine as a treatment for rapid ejaculation: a double-blind crossover trial of 15 couples. Journal of Clinical Psychiatry 1995;56(9):402-7

76) Risen CB, Althof SE. Professionals who sexually offend: evaluation procedures and preliminary findings. Journal of Sex & Marital Therapy 1994; 20(4):288-302

77) On Love, Journal of Sex & Marital Therapy 1995; 21(3):183-191

78) What is clinical sexuality? Psychiatric Clinics of North America 1995; 18(1):1-6

79) "Love" and the mental health professions: Towards an understanding of adult love. Journal of Sex & Marital Therapy 1996; 22(3)191-20

(a) Reprinted in Issues in Human Sexuality: Current & Controversial Readings with Links to Relevant Web Sites, 1998-9, Richard Blonna, Editor, Engelwood, Co. Morton Publishing Company, 1998

80) The role of Psychiatry in erectile dysfunction: a cautionary essay on the emerging

treatments. Medscape Mental Health 2(8):1997 on the Internet. September, 1997.

81) Discussion of Dr. Derek Polonsky's SSTAR presentation on Countertransference. Journal of Sex Education and Therapy 1998; 22(3):13-17

82) Understanding the sexual consequences of the menopause. Women's Health in Primary Care, 1998

(a) Reprinted in the International Menopause Newsletter

83) Fones CSL, Levine SB. Psychological aspects at the interface of diabetes and erectile dysfunction. Diabetes Reviews 1998; 6(1):1-8

84) Guay AT, Levine SB, Montague DK. New treatments for erectile dysfunction. Patient Care March 15, 1998

85) Extramarital Affairs. Journal of Sex & Marital Therapy 1998; 24(3):207-216

86) Levine SB (chairman), Brown G, Cohen-Kettenis P, Coleman E, Hage JJ, Petersen M, Pfäfflin F, Shaeffer L, vanMasdam J, Standards of Care of the Harry Benjamin International Gender Dysphoria Association, 5th revision, 1998. International Journal of Transgenderism at http://www.symposion.com/ijt

(a) Reprinted by the Harry Benjamin International Gender Dysphoria Association, Minneapolis, Minnesota

87) Althof SE, Corty E, Levine SB, Levine F, Burnett A, McVary K, Stecher V, Seftel. The EDITS: the development of questionnaires for evaluating satisfaction with treatments for erectile dysfunction. Urology 1999;53:793-799

88) Fones CSL, Levine SB, Althof SE, Risen CB. The sexual struggles of 23 clergymen: a follow-up study. Journal of Sex & Marital Therapy 1999

89) The Newly Devised Standards of Care for Gender Identity Disorders. Journal of Sex Education and Therapy 24(3):1-11,1999

90) Levine, S. B. (1999). The newly revised standards of care for gender identity disorders. Journal of Sex Education & Therapy, 24, 117-127.

91) Melman A, Levine SB, Sachs B, Segraves RT, Van Driel MF. Psychological Issues in Diagnosis of Treatment (committee 11) in Erectile Dysfunction (A.Jarden, G.Wagner, S.Khoury, F. Guiliano, H.Padma-nathan, R. Rosen, eds.) Plymbridge Distributors Limited, London, 2000

92) Pallas J, Levine SB, Althof SE, Risen CB. A study using Viagra in a mental health practice. J Sex&Marital Therapy.26(1):41-50, 2000

93) Levine SB, Stagno S. Informed Consent for Case Reports: the ethical dilemma between right to privacy and pedagogical freedom. Journal of Psychotherapy: Practice and Research, 2001, 10 (3): 193-201.

94) Alloggiamento T., Zipp C., Raxwal VK, Ashley E, Dey S. Levine SB, Froelicher VF. Sex, the Heart, and Sildenafil. Current Problems in Cardiology 26 June 2001(6):381-416

95) Re-exploring The Nature of Sexual Desire. Journal of Sex and Marital Therapy 28(1):39-51, 2002.

96) Understanding Male Heterosexuality and Its Disorders in Psychiatric Times XIX(2):13-14, February, 2002

97) Erectile Dysfunction: Why drug therapy isn't always enough. (2003) Cleveland Clinic Journal of Medicine, 70(3): 241-246.

98) The Nature of Sexual Desire: A Clinician's Perspective. Archives of Sexual Behavior 32(3):279-286, 2003 .

99) Laura Davis. What I Did For Love: Temporary Returns to the Male Gender Role. International Journal of Transgenderism, 6(4), 2002 and http://www.symposion.com/ijt

100) Risen C.B., The Crisis in the Church: Dealing with the Many Faces of Cultural Hysteria in The International Journal of Applied Psychoanalytic Studies, 1(4):364-370, 2004

101) Althof SE, Leiblum SR (chairpersons), Chevert-Measson M. Hartman U., Levine SB, McCabe M., Plaut M, Rodrigues O, Wylie K., Psychological and Interpersonal Dimensions of Sexual Function and Dysfunction in World Health Organization Conference Proceedings on Sexual Dysfunctions, Paris, 2003. Published in a book issued in 2004.

102) Commentary on Ejaculatory Restrictions as a Factor in the Treatment of Haredi (Ultra-Orthodox) Jewish Couples: How Does Therapy Work? Archives of Sexual Behavior, 33(3):June 2004

103) What is love anyway? J Sex & Marital Therapy 31(2):143-152,2005.

104) A Slightly Different Idea, Commentary on Y.M.Binik's Should Dyspareunia Be Retained as a Sexual Dysfunction in DSM-V? A Painful Classification Decision. Archives of Sexual Behavior 34(1):38-39, 2005. http://dx.doi.org/10.1007/s10508-005-7469-3

105) Commentary. Pharmacologic Treatment of Erectile Dysfunction: Not always a simple matter. BJM USA; Primary Care Medicine for the American Physician, 4(6):325-326, July 2004

106) Leading Comment: A Clinical Perspective on Infidelity. Journal of Sexual and Relationship Therapy, 20(2):143-153, May 2005.

107) Multiple authors. Efficacy and safety of sildenafil citrate (Viagra) in men with serotonergic antidepressant-associated erectile dysfunction: Results from a randomized, double-blind, placebo-controlled trial. Submitted to Journal of Clinical Psychiatry Feb 2005

108) Althof SE, Leiblum SR, Chevert-Measson M, Hartman U,Levine SB,McCabe M, Plaut M, Rodrigues O, Wylie K. Psychological and Interpersonal Dimensions of Sexual Function and Dysfunction. Journal of Sexual Medicine, 2(6): 793-800,

November, 2005

109) Shifren JL, Davis SR, Moreau M, Waldbaum A, Bouchard C., DeRogatis L., Derzko C., Bearnson P., Kakos N., O'Neill S., Levine S., Wekselman K., Buch A., Rodenberg C., Kroll R. Testosterone Patch for the Treatment of Hypoactive Sexual Desire Disorder in Naturally Menopausal Women: Results for the INTIMATE NM1 Study. Menopause: The Journal of the North American Menopause Society 13(5) 2006.

110) Reintroduction to Clinical Sexuality. Focus: A Journal of Lifelong Learning in Psychiatry Fall 2005. III (4):526-531

111) PDE-5 Inhibitors and Psychiatry in J Psychiatric Practice 12 (1): 46-49, 2006.

112) Sexual Dysfunction: What does love have to do with it? Current Psychiatry 5(7):59-68, 2006.

113) How to take a Sexual History (Without Blushing), Current Psychiatry 5(8): August, 2006.

114) Linking Depression and ED: Impact on sexual function and relationships in Sexual Function and Men's Health Through the Life Cycle under the auspices of the Consortium for Improvement of Erectile Function (CIEF),12-19, November, 2006.

115) The First Principle of Clinical Sexuality. Editorial. Journal of Sexual Medicine,4:853-854, 2007

116) Commentary on David Rowland's editorial, "Will Medical Solutions to Sexual Problems Make Sexological Care and Science Obsolete?" Journal of Sex and Marital Therapy, 33(5), 2007 in press

117) Real-Life Test Experience: Recommendations for Revisions to the Standards of Care of the World Professional Association for Transgender Health International Journal of Transgenderism, Volume 11 Issue 3, 186-193, 2009

118) Sexual Disorders: Psychiatrists and Clinical Sexuality. Psychiatric Times XXIV (9), 42-43, August 2007

119) I am not a sex therapist! Commentary to I. Binik and M. Meana's article Sex Therapy: Is there a future in this outfit? Archives of Sexual Behavior, Volume 38, Issue 6 (2009), 1033-1034

120) Solomon A (2009) Meanings and Political Implications of "Psychopathology" in a Gender Identity Clinic: Report of 10 cases. Journal of Sex and Marital Therapy 35(1): 40-57.

121) Perelman, MA., Levine SB, Fischkoff SA. Randomized, Placebo-Controlled, Crossover Study to Evaluate the Effects of Intranasal Bremelanotide on Perceptions of Desire and Arousal in Postmenopausal Women with Sexual Arousal Disorder submitted to Journal of Sexual Medicine July 2009, rejected

122) What is Sexual Addiction? Journal of Sex and Marital Therapy.2010

May;36(3):261-75

123) David Scott (2010) Sexual Education of Psychiatric Residents. Academic Psychiatry, 34(5) 349-352.

124) Chris G. McMahon, Stanley E. Althof, Joel M. Kaufman, Jacques Buvat, Stephen B. Levine, Joseph W. Aquilina, Fisseha Tesfaye, Margaret Rothman, David A. Rivas, Hartmut Porst. Efficacy and Safety of Dapoxetine for the Treatment of Premature Ejaculation: Integrated Analysis of Results From 5 Phase 3 Trials Journal of Sexual Medicine 2011 Feb;8(2):524-39.

125) Commentary on Consideration of Diagnostic Criteria for Erectile Dysfunction in DSM V. Journal of Sexual Medicine July 2010

126) Hypoactive Sexual Desire Disorder in Men: Basic types, causes, and treatment. Psychiatric Times 27(6)4-34. 2010

127) Male Sexual Dysfunctions, an audio lecture, American Physician Institute 2013

128) Fashions in Genital Fashion: Where is the line for physicians? Commentary on David Veale and Joe Daniels' Cosmetic Clitoridectomy in a 33-year-old woman. Archives of Sexual Behavior, epub ahead of print Sept 24, 2011. Arch Sex Behav (2012) 41:735–736 DOI 10.1007/s10508-011-9849-7

129) Review: Problematic Sexual Excess. Neuropsychiatry 2(1):1-12, 2012

130) The Essence of Psychotherapy. Psychiatric Times 28 (2): August 2, 2012 translated into Portuguese and republished in Revista Latinoamericana de Psicopatologia Fundamental (latin-American Journal of Fundamental Psychopathology) in press 2012.

131) Parran TV, Pisman, AR, Youngner SJ, Levine SB.Evolution of remedial CME course in professionalism: Addressing learner needs, developing content, and evaluating outcomes. *Journal of Continuing Education in the Health Professions,* 33(3): 174-179, 2013.

132) Love and Psychiatry. Psychiatric Times November 2013

133) Orgasmic Disorders, Sexual Pain Disorders, and Sexual Dysfunction Due to a Medical Condition. Board Review Psychiatry 2013-2014 Audio Digest CD 27. Audio recording of a one-hour lecture available October 2013.

134) Towards a Compendium of the Psychopathologies of Love. Archives of Sexual Behavior Online First December 25, 2013 DOI 10.1007/s10508-013-0242-6 43(1)213-220.

135) Flibanserin. (editorial) Archives of Sexual Behavior 44 (8), 2015 November 2015. DOI: 10.1007/s10508-015-0617-y

136) Martel C, Labrie F, Archer DF, Ke Y, Gonthier R, Simard JN, Lavoie L, Vaillancourt M, Montesino M, Balser J, Moyneur É; other participating members of the Prasterone Clinical Research Group. (2016) Serum steroid concentrations

remain within normal postmenopausal values in women receiving daily 6.5mg intravaginal prasterone for 12 weeks.J Steroid Biochem Mol Biol. 2016 May;159:142-53. doi: 10.1016/j.jsbmb.2016.03.016

137) Reflections of an Expert on the Legal Battles Over Prisoners with Gender Dysphoria. J Am Acad Psychiatry Law 44:236–45, 2016

138) Cooper E, McBride J, Levine SB. Does Flibanserin have a future? Psychiatric Times accepted October 23, 2015.

139) Levine SB, Sheridan DL, Cooper EB. The Quest for a Prosexual Medication for Women, Current Sexual Health Reports (2016) 8: 129. doi:10.1007/s11930-016-0085-y

140) Why Sex Is Important: Background for Helping Patients with Their Sexual Lives., British Journal of Psychiatry Advances (2017), vol. 23(5) 300-306; DOI: 10.1192/apt.bp.116.016428

141) Flibanserin: Offene Forshungsfragen , Zeitschrift für Sexualforschung. 29: 170-175, 2016. This is a translation of (134).

142) Commentary on "Asexuality: Orientation, paraphilia, dysfunction, or none of the above? Archives Sexual Behavior, Archives of Sexual Behavior April 2017, Volume 46, Issue 3, pp 639–642 DOI: 10.1007/s10508-017-0947-z

143) Sexual Dysfunction in Clinical Psychiatry, Psychiatric Times, March 2017

144) Ethical Concerns About the Emerging Treatment of Gender Dysphoria. Journal of Sex and Marital Therapy, 44(1):29-44. 2017. DOI 10.1080/0092623X.2017.1309482

145) The Psychiatrist's Role in Managing Transgender Youth: Navigating Today's Politicized Terrain. CMEtoGO® Audio Lecture Series, May 2017

146) Transitioning Back to Maleness, Archives of Sexual Behavior, 2017 Dec 20. doi: 10.1007/s10508-017-1136-9. [Epub ahead of print]; 47(4), 1295-1300, May 2018

147) Informed Consent for Transgender Patients, Journal of Sex and Marital Therapy, 2018 Dec 22:1-12. doi: 10.1080/0092623X.2018.1518885. [Epub ahead of print]

C) Chapters

1) Overview of Sex Therapy. In Sholevar GP (ed) The Handbook of Marriage and Marital Therapy. New York. Spectrum Publications, 1981 pp417-41

2) Why study sexual functioning in diabetes? In Hamburg BA, Lipsett LF, Inoff GE, Drash A (eds) Behavioral & Psychosocial Issues in Diabetes: Proceedings of a National conference. Washington, DC. US Dept. of Health & Human Services. PHS NIH, Pub. #80-1933

3) Sexual Problems in the Diabetic in Bleicher SJ, Brodoff B (eds) Diabetes Mellitus and Obesity. Williams and Wilkins, 1992